510(k) Summary

Trade name:	***Accu-pulse*** TENS unit
Common name:	TENS unit.
Manufactured by:	Sadler Electronics.
Contact person:	C.A. Sadler 3 Coetzenberg Road Edgemead 7441 South Africa. Tel. +27 21 5584088
Date of preparation:	11th January 2001
Description:	Transcutaneous electrical nerve stimulator for pain relief
Intended use:	Relief of chronic intractable pain.

Description: The *Accu-pulse* is a conventional Tens unit having a fixed pulse length (120 microsecond) and pulse frequency (60pulses/ second). The pulse parameters are fixed at what is felt to be the most effective settings, since providing a wide choice of adjustments can be confusing and result in the use of less effective settings. The output level is adjustable from 0-80 Volts. Two types of output are available, namely continuous and pulse-train TENS. It is battery powered.

This 510(k) submission demonstrates the substantial equivalence of the Accupulse to ten predicate devices named on page 5. The Accu-pulse is shown to be identical to the predicates in respect of Indications for use, user group, mode of operation, manner of usage, and virtually identical as regards electrical output. No new claims are presented regarding efficacy. The electrical modus operandi and circuit configuration will be seen to be "conventional" for TENS units, no new features are contained therein.
The Accu-pulse was designed using the same safety standards to which the predicates are subject, and all electrical output parameters are within the limits imposed for this class of device.
The expected result of treatment, possible side effects, precautions to be observed, contraindications and warnings required are the same as the predicates.

This submission was prepared with the help of the following documents:

Guidance for TENS 5 10(k) content
How to prepare a conventional 510(k)
How to prepare an abbreviated 5 10(k)
510(k): regulatory requirements for medical devices
Getting to market with a medical device
How to market a 5 10(k) device
An introduction to medical device regulations
Use of standards in substantial equivalence determinations
Performance standard for electrode lead wires and patient cables
Guidance for 5109k) content
Medical devices; establishment of a performance standard for lead wires
IIEC 606 1-1 Safety standards for electromedical devices (in general)
LEC 6061-2-10 safety standards for TENS units!

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 8 2001

Mr. C. A. Sadler
Sadler Electronics
3 Coetzenberg Road
Edgemead 7441
South Africa

Re: K010203
Trade Name: Accu-pulse Tens Unit
Regulation Number: 21 CFR 882.5890
Regulatory Class: II
Product Code: GZJ
Dated: Undated
Received: June 4, 2001

Dear Mr. Sadler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010203

Device Name: Accu-pulse TENS unit

Indications For Use:

ONLY FOR THE RELIEF OF CHRONIC INTRACTABLE PAIN.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhouse

(Division Sign-Off)
Division of General, Restorati...
and Neurological Devices

510(k) Number K010203

(Optional Format 3-10-98)